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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/668,785

09/23/2003

Troy M. Just

4104

31083

7590

05/19/2006

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EXAMINER

HAND, MELANIE JO

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/668,785	<b>Applicant(s)</b> JUST, TROY M.	
	<b>Examiner</b> Melanie J. Hand	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,8,10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,8,10 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments filed February 21, 2006 have been fully considered but they are not persuasive. With respect to applicant's argument that Examiner's rejection of claims 1-5 and 8-14 under 35 U.S.C. 102, in response, it is noted that the features upon which applicant relies (i.e., that the piston remains in the barrel ensuring that the applicator may not be reused) were not recited in the rejected claim(s) at the time the previous Office action was mailed. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrer et al (U.S. Patent No. 6,364,854).

With respect to **Claims 1,8**: Ferrer teaches vaginal medication applicator 10 comprising main tubular body 20 having an inner surface, plunger 30, piston 40 and cap 50. Main body 20 has a closed dispensing end 21 with a plurality of openings 26 and an open grasping end 22. Piston 40 is slidably mounted on a rod within said main body 20 and is therefore capable of being selectively positioned. Piston 40 fits snugly within section 23 of the main applicator body and provides a closure to the compartment wherein medication is stored and has sealing flange 43

disposed on its outer surface that engages with the inner surface of section 23 of body 20. As can best be seen in Fig. 5, an opening 45 is present in piston 40 to accept plunger 30 and this opening terminates between the first and second ends of said piston. Plunger 30 and piston 40 are configured so as to fit together to form the impeller system for dispensing the medication outward from said body 20. Plunger 30 has inner end 31 that is always housed inside body 20 and is slidably engageable with piston 40. Piston 40 has an outer diameter that is larger than body 20 due to the presence of flange 43, therefore said piston is in a compressed state whenever it is disposed within body 20. Due to this compression, upon application of force to piston 40 by plunger 30, piston 40 is pushed along body 20 toward dispensing end 21 while being longitudinally stretched. Pairs of elements 46-35 and 47-34 act to retain the piston in an engaged position at one end of the plunger, allowing discharge of medication and preventing accidental disassembly of the plunger-piston system while the applicator is being used. (Col. 2, lines 51-65, Col. 4, lines 14-17, 20-27, 36-40, 49-53, 57-67, Col. 5, lines 22, 23, 28-35, Col. 7, lines 11,12)

Ferrer teaches that the piston and plunger are an effectively unitary impeller means in that when the applicator is manufactured, the piston and plunger are assembled together in an engaged configuration. Therefore, when the impeller means is advanced to propel medication out of the end of the applicator, both the piston and the plunger remain in the barrel to ensure that the applicator is not re-usable. Ferrer thus does not explicitly teach that the plunger as it exists within an assembled applicator, is detachably connected to the piston in such a manner as to be capable of being disconnected from said piston, thereby leaving the piston in the main body portion. However, it would be obvious to one of ordinary skill in the art to modify the applicator of Ferrer to be manufactured separately from the piston in such a way as to allow the plunger to disconnect from the piston upon completion of use, as these pieces are

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manufactured separately and are capable of being assembled separately as an alternative means of assembling that produces a substantially identical product to the claimed invention. Rejection under 35 U.S.C. 103 is indicated where prior art discloses product that appears to be either identical with or only slightly different from product claimed in product-by-process claim. See *In re Fitzgerald, Sanders, & Bagheri*, 205 USPQ 594 (CCPA 1980).

With respect to **Claims 2,10**: Ferrer teaches that piston 40 fits snugly within portion 23 of body 20 and is thus receivable in openings 26. (Col. 4, lines 19,20)

With respect to **Claims 3,11**: Since Ferrer teaches that piston 40 and plunger 30 are assembled together and are constructed in a complementary manner such that plunger 30 having rib 34 and groove 35 engage piston 40 via orifice 45 to lock the piston 40 in place, forming an effectively unitary impeller structure. Therefore, application of a certain amount of force against the first end of the plunger 30 that is disposed within orifice 45 of piston 40 will result in the destruction of the impeller system, thus ensuring that the applicator cannot be reused.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie J Hand  
Examiner  
Art Unit 3761

MJH

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

